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Ms. Marina Lamm
Examiner
Art Unit 1616
Assistant Commissioner for Patents
Washington, D.C 20231

RE: US Application Number 09/682249 Filed 08/09/2001

**Title: NON-ENDOCRINE DISRUPTING CYTOPROTECTIVE UV RADIATION
RESISTANT COMPOSITION**

Dear Examiner Lamm,

Thank you for granting the in-office interview on 7/17/02 regarding U.S. utility application 09/682249 from 1 –2 PM. In accordance with MPEP 713.04, and 37 CFR 1.133 (b) and compliance with the 30 day time limit, please find a more detailed and accurate record of what was discussed and agreed to at this interview session regarding the present invention. A copy of your Interview Summary form PTOL 413 is attached.

A complete response to your office action of 2/28/2002 will also be forthcoming within the next week with the allocated fee for a 3 month extension.

With best personal regards,


Guerry L. Grune

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STATEMENT OF THE SUBSTANCE OF THE INTERVIEW: (Optional)

Submitted August 9, 2002

Application Number: 09/682,249

Title: NON-ENDOCRINE DISRUPTING CYTOPROTECTIVE UV RADIATION RESISTANT COMPOSITION

Name of Applicant: Guerry L. Grune

Name of Examiner: Marina Lamm

Date of Interview: July 17, 2002

Type of Interview: Personal

Name of Participants: Applicant (who is also Agent) and Examiner Only

Exhibit was shown (actually 2)

Identification of the specific prior art discussed (see below)

General Agreement was reached (based on discussion with examiner as stated and documented and memorialized below)

Examiner signed the Interview Summary

Summary of the 7/17/02 interview regarding USP Application Number 09/682,249 with examiner Marina Lamm;

Patent practitioner and inventor Guerry L. Grune met with Examiner Lamm from 1:00 PM – 2:10 PM in her office at the USPTO to discuss the 1st Office Action objections and rejections regarding USP application number 09/682,249. The interview started by G. Grune giving examiner Lamm 2 samples of the sunblock which were representative of the invention.

Next, G. Grune requested (and Ms. Lamm agreed) to go through the Office Action in a step-by-step orderly fashion. This was accomplished as follows;

G. Grune did not try to reargue the Restriction requirement by Ms. Lamm. Therefore the interview was directed only to the Office Action dated 2/28/2002.

G. Grune understood the objection under 37 USC 1.75 (c) regarding improper claim form for claims 26 and 27. G. Grune stated that he would omit the word “and” and insert the word “or”. Examiner Lamm agreed that this would be persuasive but only if claims 12, 23, and 24 were cancelled due as required by the Election after the Restriction

Examiner Lamm explained that a divisional can be filed to copend with the parent application. The non-elected claims would then be canceled by Preliminary Amendment and prosecution of this separate application could proceed.

Claim 25 was not discussed, but it will be amended or cancelled as necessary to overcome the 35 USC 101 Double Patenting rejection.

Next, G. Grune explained the inventive concept and how claim 1 and all subsequent claims dependent on claim 1 were enabling to one skilled in the art. G. Grune explained that in addition to the article referenced in the specification to Margeret Schlumpf, a list of known or suspected endocrines is on a website posted by EPA, so that “one skilled in

the art” would immediately understand and recognize the differences between endocrine disruptive substances and those that are non-endocrine disruptive. Examiner Lamm understood and stated that the phrase “wherein the non-endocrine disruptive components....” should be inserted into the claims where non-endocrine disrupting agents are required. Ms. Lamm stated that it was of utmost importance to show where there was support for these claims in the specification (and these were shown – on page 1, lines 18-22 of page 10, lines 42-44 of page 11, etc of the applicant’s copy of the specification). Ms. Lamm added that because the prior art has both endocrine and non-endocrine disrupting agents, it must be made very clear how one “skilled in the art” would know which are which. Ms. Lamm stated that the EPA specific website address could be inserted in an IDS along with Margeret Schlumpf’s article and it could be used as an exhibit in the rebuttal to the 35 USC 112 rejection.

Next came a discussion on the situation regarding indefiniteness. Basically, the inconsistency of using the words sunblock and sunscreen caused the examiner undue confusion and G. Grune apologized for the inconsistencies in the claim language. It was stated by G. Grune and agreed by Examiner Lamm that the composition was that of a sunblock, not a sunscreen and the amended claims must be consistent in that regard. Ms. Lamm understood that the antecedent basis rejection could be easily removed and that the language “consisting essentially of” might be helpful in overcoming any of the 35 USC 112 second paragraph rejections. Sunscreen compositions that are non-endocrine disrupting would only be claimed in accordance with the reference to butyl-methoxydibenzoylmethane and esters of the like as listed on page 10 of the applicant’s copy of the application.

It was then explained, in great detail, that the invention is descriptive of a new composition, one which cannot be found on any retail shelves (Examiner Lamm told G. Grune she found sunblock using titanium dioxide or zinc oxide during her search) that is a combination of the following;

Cold pressed aloe – processing allows for retention of all cytoprotective agents in natural aloe

No known endocrine disrupters – well known to those “skilled in the art”

Only titanium dioxide or zinc oxide as the sunblock agent – and only one known organic sunscreen agent could be used – that stated in the specification – and was pointed out to Examiner Lamm – on page 10 of applicant’s copy – butyl-methoxydibenzoylmethane – because this substance has NOT been found to be an endocrine disrupter.

It was further explained to Examiner Lamm that based on documented effects with regard to endocrine disrupters (early onset of puberty in adolescents – particularly females, the hermaphroditic insects, birds and fish that have been found in the environment, etc.), that there would most likely be a depressed immune system response in the presence of UV radiation and its already well documented harmful effect on mammalian skin. This response is unacceptable and more importantly unnecessary with the proper sunblock formulation which led to the present invention and the filing of this application.

Examiner Lamm stated that this composition must be clearly stated and defined in the claims. Ms. Lamm made it very clear that it was the inventor/agent's responsibility to show exactly where in the specification there is support for the claim(s) and that this showing of support together with the removal of the words "preferred" would overcome the 112 rejection.

Next, Ms. Lamm stated she was most concerned about the 102 rejections. Specifically it must be shown that the present invention has no known endocrine disrupters as she agreed that the cited patents; 5,980,871 and 5,972,362 and 5,824,659 do not make reference to endocrine disrupters or agents thereof. It is imperative that the inventor/agent show the specific differences in composition between the known prior art and the present invention. Again, Examiner Lamm stressed the need to show support from the specification and exactly where in the specification the support exists.

Examiner Lamm ended the interview with another review of the Wenker patent, USP 5,972,362, which indicates only one example of a sunscreen composition – that which includes the use of glycerin, titanium dioxide and an aloe vera gel. G. Grune indicated that the glycerin was not vegetable based, and Examiner Lamm stated that it was broad enough to include vegetable or non-vegetable based glycerin and would still offer a rejection based on that possibility. G. Grune then stated that the aloe was not "cold pressed" to which Examiner Lamm replied "is that important?" G. Grune stated it was of utmost importance because of the cytoprotective nature and qualities of the aloe if it is processed by what are currently very unconventional methods. Examiner Lamm understood, agreed, and stated that this needed to be explained in the response to overcome the rejections made under 102 and then again under 103.

It was also re-emphasized by G. Grune that there is no restriction regarding the use of only non-endocrine disrupting agents in the cited prior art or any other known art. Examiner Lamm understood and agreed to the proposed changes by amendment with the proviso that all amendments find support in the specification and are cited as to where they occur in the specification.

The interview ended at approximately 2:10 PM and then, at the request of G. Grune, to make the further and future examination proceed more smoothly, Examiner Lamm made a copy of her (electronically filed) version of the application so that G. Grune can point out specifically where the specification makes reference to what will become the amended claim(s) based on her office action of 2/28/02. G. Grune left Examiner Lamm's office at approximately 2:30 PM after thanking her for her time and for coming to the office specifically to meet with G. Grune while she is on maternity leave.